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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,542	03/04/2002	Nikolay V. Kuchuk	ICON-001	5528
530	7590	04/17/2006	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			FOX, DAVID T	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,542

Applicant(s)

KUCHUK ET AL.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/5/05 & 2/3/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 25-32 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/15/01; 11/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The copies of the Information Disclosure Statements sent in the last Office action were incorrect in their indication that some references were not submitted by Applicant. Properly executed IDSs are attached to the instant Office action.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. The Office is unable to use the provided first page of the PCT document as an abstract.

The amendment of 05 December 2005 has obviated the outstanding rejection under 35 USC 101.

Claims 1-24 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method for introducing into any plant species any "excisable flanking sequence" of any sequence and any length (claim 1) encoding any type of product, including any transposon (claim 2) and any recombinase system (claim 3). In contrast, the specification only provides guidance for cruciferous plant transformation with a single transposase sequence. No guidance has been provided for the characterization of a multitude of sequences which are somehow "excisable", including a multitude of transposons and a multitude of non-exemplified recombinase

sequences. Furthermore, no guidance has been provided for the reduction to practice of a multitude of transformed plants of a multitude of unrelated species such as maize, potato, tobacco, cotton or soybean, or their wild relatives.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying

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characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claims 1-24 and 33-35 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on pages 4-12 of the last Office action.

In addition to the comments provided in the last Office action, the enablement rejection is supplemented with the following comments set forth below.

The claimed method of using recombinase-encoding sequences and recombinase recognition sequences for the controlled excision of DNA, and its

concomitant excision and transfer from one plant to another following their crossing, is unpredictable.

The use of sexual crossing to introduce the recombinase-encoding sequence has only resulted in partial excision of the gene of interest, due to lateness or inefficiency of expression (see, e.g., Zhang et al, page 1167, column 2, first full paragraph).

In an analogous situation, the use of re-transformation to introduce a recombinase-encoding sequence in plants which already contain the recombinase recognition sequences is also unpredictable. Dale et al teach that the subsequent transformation of plants with the recombinase sequence, which plants already contained the marker gene, resulted in only 50% excision of the gene of interest (see, e.g., page 10559, column 2, penultimate paragraph). Gleave et al teach that re-transformation with the recombinase gene, or transient expression thereof, failed to completely excise a conditional lethal dominant gene from plant cells and plants regenerated therefrom (see, e.g., page 223, Abstract; page 232, column 1, to paragraph). Gleave et al also teach that the recombinase coding sequence had been unpredictably integrated into the plant cell genome (see, e.g., page 233, column 1, top paragraph).

Applicant's arguments filed 05 December 2005 and 03 February 2006 have been fully considered but they are not persuasive. Applicant urges that the enablement rejection is improper, given the exemplification of a transposon-mediated method for DNA transfer in the wide cross of *Orychophragmus X Sinapsis*, the disclosure in the specification of a variety of species pairs for use in wide crosses, and the availability of

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recombinase/recombination recognition sequence systems for plant transformation.

Applicant further relies upon the Klimyuk declaration of 03 February 2006 which asserts that the method of Example I in the specification could be reasonably extrapolated to any other species pair, given the demonstration of pearl millet chromosome loss in a pearl millet X wheat interspecific cross as set forth in Gernand et al (2005). The Klimyuk declaration also asserts that subsequent to the filing of the instant application, transposition experiments have been performed with a cross between two *Nicotiana* species.

The Examiner maintains that evidence has been provided in this and previous Office actions regarding the unpredictability inherent in recombinase/recombination recognition sequence-mediated gene excision in plants, particularly when sexual crossing is employed; or when other methods to introduce the recombinase-encoding sequence and the recombination recognition sequences in different plants, followed by methods for their recombination into a single plant, are employed. Such evidence is more probative than Applicant's mere assertions to the contrary.

Regarding the study of pearl millet chromosome loss in a pearl millet X wheat interspecific cross, it does not appear that transposons or other site-specific recombination systems were employed or evaluated. It is noted that no copy of Gernand et al was provided by Applicant.

Regarding the above-mentioned *Nicotiana* experiment, it is noted that this experiment was merely anecdotally reported in the Klimyuk declaration. The Examiner is unable to determine whether the starting materials and methods of the instant

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specification were employed, or whether success was obtained, in the absence of disclosure of any experimental protocols or data.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Federoff (US 4,732,856).

The claims are broadly drawn to whole plants of any species containing a heterologous nucleic acid which was introduced via excisable flanking sequences including transposon sequences, and seeds and progeny thereof which also contain said heterologous nucleic acid sequences. The claims recite that the plants were produced via crossing two different plant species, wherein unstable progeny were produced which lost the genome of the first plant species, wherein the heterologous nucleic acid was maintained in the genome of progeny plants of the second species.

Federoff teaches a method for introducing heterologous nucleic acids comprising marker genes into plants, wherein the heterologous nucleic acids are part of a transposon, and are therefore flanked by excisable transposon sequences, wherein said heterologous nucleic acids are stably inherited through the progeny of said plants (see, e.g., column 23, line 3 through column 25, line 42; claims 14-20). Seeds and progeny of the transposon-transformed plants containing the “heritable” heterologous nucleic acid would have been inherent products of the claimed method.

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Federoff does not teach the use of interspecific crossing to produce transposon-transformed plants. However, as admitted by Applicant, the desired progeny have lost all of the genome of the first interspecific parent, and retain the genome of the second interspecific parent, which second parent also retains the transposon sequence-flanked heterologous nucleic acid. Thus, the plants taught by Federoff are indistinguishable from the claimed plants, despite their alternate method of production.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Claims 1-24 remain free of the prior art, given the failure of the prior art to teach a method for plant transformation comprising interspecific crossing combined with the introduction of excisable flanking nucleotide sequences, wherein the products of said crossing are unstable and result in the genomic loss of one of the parents of the cross, while retaining the heterologous nucleic acid.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 13, 2006

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

